LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Hyprosan
(hypromellose)

SE/H/1171/01/DC

This module reflects the scientific discussion for the approval of Hyprosan. The procedure was finalised at 2012-11-27. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

Santen Oy has applied for a marketing authorisation for Hyprosan, eye drops, solution, 3.2 mg/ml, claiming essential similarity to Artelac, eye drops, solution, 3.2 mg/ml, marketed in Sweden by Santen Oy. The product contains hypromellose as active substance. For approved indications see the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

Hyprosan is presented in the form of eye drops, solution containing 3.2 mg of hypromellose. The excipients are cetrimide, disodium phosphate dodecahydrate, sodium dihydrogen phosphate dihydrate, disodium edetate, sorbitol and water for injections. The eye drops are filled in transparent plastic (LDPE) bottle containing 10 ml of solution, with dropper tip and white HDPE cap.

II.2 Drug Substance

Hypromellose has a monograph in the Ph Eur.

Hypromellose is a white, yellowish-white or greyish-white powder or granules that are hygroscopic after drying which is practically insoluble in hot water and dissolves in cold water giving a colloidal solution. The structure of hypromellose has been adequately proven and its physico-chemical properties sufficiently described. The route of synthesis has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.

The active substance specification includes relevant tests and the limits for impurities/degradation products have been justified. The analytical methods applied are suitably described and validated.

Stability studies under ICH conditions have been conducted and the data provided are sufficient to confirm the retest period.

II.3 Medicinal Product

Hyprosan eye drops, solution is formulated using excipients described in the current Ph Eur. All raw materials used in the product have demonstrated compliance with Commission Directive 2003/63/EC and the NfG on Minimising the risk of transmitting Animal Spongiform Encephalopathy Agents via human and veterinary medicinal products (EMEA/410/01).

The product development has taken into consideration the physico-chemical characteristics of the active substance, such as aqueous solubility.

The manufacturing process has been sufficiently described and critical steps identified. Results from the process validation studies confirm that the process is under control and ensure both batch to batch reproducibility and compliance with the product specification.

The tests and limits in the specification are considered appropriate to control the quality of the finished product in relation to its intended purpose.

Stability studies under ICH conditions have been performed and data presented support the shelf life and storage conditions claimed in the SPC.

III. NON-CLINICAL ASPECTS

III.1 Discussion on the non-clinical aspects

Since this product has been shown to be essentially similar and refers to a product approved based on a full application with regard to preclinical data, no further such data have been submitted or are considered necessary.

IV. CLINICAL ASPECTS

IV.1 Discussion on the clinical aspects

Since this product has been shown to be essentially similar and refers to a product approved based on a full application with regard to clinical efficacy/safety data, no further such data have been submitted or are considered necessary.

V. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

User consultation
The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The language used for the purpose of user testing the PIL was English.
The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

The SmPC, PL and labelling text is considered acceptable.

The risk/benefit ratio is considered positive and Hyprosan, eye drops, solution, 3.2 mg/ml is recommended for approval.

VI. APPROVAL

The Decentralised procedure for Hyprosan, eye drops, solution, 3.2 mg/ml was successfully finalised on 2012-11-27.

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Public Assessment Report – Update

Scope	Procedure number	Product Information affected	Date of start of the procedure	Date of end of procedure	Approval/ non approval	Assessment report attached
						Y/N (version)

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